IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF TEXAS AUSTIN DIVISION

RAVGEN, INC.,

Plaintiff,

Civil Action No. 1:20-cv-00692-ADA

JURY TRIAL DEMANDED

NATERA, INC. AND NSTX, INC.,

v.

Defendants.

ORDER REGARDING PLAINTIFF RAVGEN, INC.'S DISCOVERY DISPUTE REQUESTS

Before the Court are two discovery disputes between Plaintiff Ravgen, Inc. ("Ravgen") and Defendants Natera, Inc. and NSTX, Inc. ("Natera") in the above-captioned action, which arose via the Court's OGP discovery dispute process. Ravgen seeks an order (1) precluding Natera from relying on certain prior art and prior art combinations included in Natera's June 28, 2023 identification or prior art combinations; and (2) striking Natera's disclosure of Wolfgang Holzgreve and Daniel Collins in Natera's Third Supplemental Initial Disclosures dated June 23, 2023. Parties respective arguments were submitted in the chart below:

Issue	Ravgen's Position	Natera's Position
Natera's	Natera is seeking to re-do its invalidity	The Court already resolved this
assertion of	case by asserting, as of June 28, 2023,	dispute at the 5/22/2023
ten new prior	ten new prior art combinations,	hearing. Ravgen seeks to
art	including three new references, that	fundamentally change its
combinations,	Natera failed to pursue since this case	infringement case through a new 69-
including	began three years ago in June 2020,	page expert declaration, a new
three new	and failed to disclose in its invalidity	infringement theory based on new
prior art	contentions or <i>nearly two years ago</i> in	testing, and new documentary
references,	September 2021 when Natera	evidence about the Streck Tube's
disclosed on	identified its final fourteen invalidity	purported contents. Dkt.

June 28, 2023.

theories for trial. The Court should preclude Natera's new theories.

Natera alleges it should get a do-over on validity because: (1) Natera lost at summary judgment on its proposed construction of the Patents-in-Suit's "agent" term via the Court's Supplemental Construction (Dkt. 176); and (2) a false assertion that Ravgen "changed" its infringement theories, necessitating a "response" (no such change exists). Natera's new theories are improper and should be precluded. There have been no changes to this case warranting new invalidity theories, Natera was not diligent in pursuing them, and they will cause Ravgen substantial prejudice.

First, there are no claim construction "changes" warranting new theories. The language of the Construction Supplemental that Natera asserts warrants its new theories was disclosed before fact discovery. Indeed, Ravgen proposed during Markman nearly identical language excluding anticoagulants and endogenous substances from the "agent" term that the Court correctly adopted in its Supplemental Construction. Compare Dkt. 46 at 9 (Ravgen proposing plain and ordinary meaning of "agent" as "a substance that...does include...anticoagulants and chelators EDTA, \bigcap or endogenous substances...."); with Dkt. 176 at 1 (Court construing "agent" as "a substance that...does not include chelators used as anticoagulants []or endogenous substances."). Courts routinely deny invalidity supplementations even *before*

281. Moreover, since the original discovery period closed, a new claim construction Order issued that Ravgen seeks to address with this new evidence. *Id.*; Dkt. 176. Yet Ravgen seeks to block Natera from supplementing in response.

Two judges have already rejected Ravgen's one-sided approach:

"I'm going to allow both sides, whoever goes first, whoever launches the missiles first, *the other side is going to get to adequately...respond to anything.*" Tr. 28-29 (Albright).

- 1. "[A]s long as you, the plaintiff, have an opportunity to do sufficient preparation with the defendant, I'm probably going to be pretty liberal at what I allow them to add in their expert report." Id.
- 2. "If I were to reopen the record, it's going to apply to both of you. It would never be my intention to allow one side to do what they want to do and the other side not to be allowed to answer it." 2/28/2023 Hr'g Tr. 13 (Yeakel).

That is the right result.

First, Natera should be permitted to respond to the new construction of the "agent" term. At Markman, the Court construed "agent" to have its plain meaning, see Dkt. 95, and Natera elected its invalidity theories (and prior based art) on that construction. After expert discovery closed. issued the Court construction—different from what either party proposed—finding a

summary judgment when cause construction does not surprise. See ACMEWorldwide Enterprises, Inc. v. United States, No. 17-843, 2022 WL 6853387, at *3 (Fed. Oct. 11, 2022) (denying supplementation where movant "fail[ed] to explain how" construction "was unexpected"). There is even less reason to do so almost two years after summary judgment. Further, while Natera's counsel thinks this Court "doesn't understand the technology at issue," May 22, 2023 Hearing Transcript ("Tr") at 11, Natera's disagreement with the Supplemental Construction is not a basis for a doover. Iovate Health Scis., Inc. v. Bio-Engineered Supplements & Nutrition, Inc., No. 9:07-cv-00046, 2008 WL 11344914, at *2 (E.D. Tex. Aug. 7, 2008) ("A party cannot argue that because its precise [construction]...is not adopted...[it] must prepare new [i]nvalidity [c]ontentions").

Ravgen also has not "changed" its infringement theories. Ravgen has asserted since this case began that Natera infringes by, among other things, using formaldehyde in Streck Tubes to inhibit cell lysis in Natera's cell-free DNA assays. *See, e.g.,* Dkt. 116, Ex. 1 at 173. When Ravgen asked Natera what "change" to its infringement theory Natera must "respond" to, Natera could not identify one (none exists).

Ravgen did recently produce documents on which it intends to rely, but those documents were either not available until after the original close of discovery or were *disclosed years* ago. And critically, those documents support the same theories Ravgen

disclaimer of certain prior art. Dkt. 176. Natera should be permitted to adjust its invalidity theories in response. E.g., Asyst Techs., Inc. v. Emtrak, Inc., 544 F.3d 1310, 1317 (Fed. Cir. 2008) ("change in claim construction resulting from court's decision on appeal 'changed rules the ofgame,'[;]...[defendant] was therefore properly permitted to amend its defenses"). Neither Ravgen's misleading quotation of Natera's counsel, nor the district court cases Ravgen cites, support a different result. Neither case involved a new claim construction issued after the close of discovery.

Second, Natera should get to supplement in response to the significant changes Ravgen is making to its infringement case. While the case was stayed, Ravgen successfully argued to the PTAB that the "agent" limitation is met only if there is evidence that the "agent" inhibits cell Supplemental Claim lysis. The Construction Order also finds that the "agent" must inhibit lysis if cells are present. Dkt. 176 at 11. Yet, during the original discovery period, Ravgen failed to come forward with any testing of the alleged "agent" in the Streck Tubes. Ravgen's new testing is—despite its claims otherwise—a fundamental change to its case that Ravgen first sought (unsuccessfully) to inject months after the original discovery period. If Ravgen is now permitted to change its infringement case in this manner, then because Natera's invalidity arguments are necessarily responsive to Ravgen's infringement case, Natera should be permitted to show how, if the claims

previously disclosed. For example, Ravgen produced a handful of records improperly withheld Streck responding to Ravgen's subpoena in this case but produced following motions to compel Streck in other The remaining documents cases. include those attached to an expert served upon Natera report November 2021 or included on an exhibit list served by Natera in October 2021.

Second, Natera's new theories should be precluded because Natera was not diligent in identifying them. Sorenson and Hahn (two of the three new references, in addition to product StabilCyte) appeared in third-party IPR petitions concerning the same Patents-in-Suit in April 2021—three months prior to the original close of fact discovery. Thus, Natera "had [the references] and [] didn't do anything with [them]." Tr. at 16 (referring to separate, previously-undisclosed defense). Indeed, "had the case gone to trial" in 2021, Natera "wouldn't have raised [these] defense[s.]" Id. at 19 (same). This is therefore not a situation where art is uncovered "at the very last moment." Id. at 21; accord Tr. at 22.

Third, at this late stage, Natera's new, previously-unpursued theories will cause Ravgen substantial prejudice. See, e.g., id. at 19 ("The prejudice is overwhelming in this case that had the case gone to trial when it was scheduled..., you wouldn't have raised this defense[.]"); id. at 22. Ravgen's substantial prejudice includes the waste of resources Ravgen must expend re-writing its expert reports for ten new invalidity

are stretched the way Ravgen proposes, the claims are also invalid over the StabilCyte product prior art.

Ravgen is wrong that Natera was not "diligent." Natera based its previous invalidity defenses on the existing claim construction and Ravgen's prior infringement arguments. Now that both have changed, Natera should be allowed to respond accordingly.

Third, Natera's supplementation will not unfairly prejudice Ravgen. Ravgen is well aware of each prior art reference, each of which has been raised in prior Ravgen cases. Ravgen will have a full opportunity to respond to Natera's theories. Mortg. Grader, Inc. v. First Choice Loan Servs. Inc., 811 F.3d 1314, 1323 (Fed. Cir. 2016) (no unfair prejudice when plaintiff opportunity to respond). It is Natera that would be unfairly prejudiced if not allowed to supplement.

Ravgen's "prejudice" argument relies solely on out-of-context quotations from the 5/22/2023 hearing. *Every quotation* Ravgen included relates to Natera's motion to amend to add a release defense. But when addressing supplementation, the Court made clear—in portions of the transcript Ravgen ignores—that Natera was "going to get to adequately...respond to anything." Tr. 28-29.

Requested Relief. Order that "Natera is permitted to assert the prior art combinations that it disclosed on June 28, 2023."

theories and necessarily serving a new third-party subpoena concerning StabilCyte. This case was trial ready in 2021. Ravgen should not be forced to completely re-do its expert reports or seek third-party discovery now just so Natera can assert defenses it never pursued.

Requested Relief: Order that "Natera is precluded from asserting new prior art combinations that it did not disclose to Ravgen in its identification of prior art theories served on September 24, 2021."

Natera's identification of two new third-party fact witnesses on June 23, 2023.

The Court should strike Natera's disclosure of new fact witnesses, Wolfgang Holzgreve and Daniel Collins, from Natera's Third Supplemental Initial Disclosures.

On June 23, 2023, Natera disclosed Holzgreve and Collins as allegedly having "factual information" concerning Ravgen's alleged invention and StabilCyte (referenced above), respectively. Natera knew or should have known about Holzgreve and Collins prior to the original close of fact discovery in July 2021. Papers authored by Holzgreve appear on the face of the Patents-in-Suit. More importantly, Ravgen produced additional Holzgreve papers December 2020, and Natera cited those papers in its expert reports. See, e.g., Dkt. 154, Ex. 6 at 24. Natera never once suggested it would bring Holzgreve to trial until June 23. As for Collins, his alleged "relevance" is just a consequence of Natera's diligence in pursuing invalidity failure (described above).

The same prejudices above apply equally here. A new subpoena for

This is effectively the same issue as above that was resolved at the 5/22/2023 hearing. Ravgen is seeking to remake its case with new theories and evidence while trying to prevent Natera from reciprocal supplementation.

Holzgreve First. Dr. has undisputedly relevant. contemporaneous factual information. His testimony relevant to enablement under the Supplemental Claim Construction Order requiring that the "agent" must inhibit lysis of cells. Ravgen claims that this inhibition results in an increase of the percentage of fetal DNA in a sample. Holzgreve would testify that his own contemporaneous study showed that no such increase occurred—evidence the claims are not enabled.

Second, Ravgen's assertion that Natera could have decided to call Holzgreve earlier misses the point. Ravgen also could have performed infringement testing in its original expert reports but did not—resulting in a failure of proof. The

Holzgreve is particularly necessary because, after Quest (who was also represented by Natera's new counsel, WilmerHale) identified him on its initial disclosures, a significant issue arose regarding the exorbitant fees Quest was paying him (and other fact witnesses) for factual testimony. Thus, allowing Holzgreve to testify would require subpoenaing him in this case to see how much Natera is paying him. Ravgen must also subpoena Collins for the same reason and those above.

Requested Relief: Order that "Natera's disclosure of Wolfgang Holzgreve and Daniel Collins in its Third Supplemental Initial Disclosures dated June 23, 2023, is hereby STRICKEN."

changed circumstances—including Ravgen's testing and the new claim construction—made Holzgreve more relevant.

Third, there is no unfair prejudice. Ravgen admits Holzgreve's articles are already cited in expert reports. Moreover, Ravgen already deposed Holzgreve in another case; he is available for deposition again here; and there is sufficient time to take a deposition before trial.

Ravgen's suggestion that Holzgreve was paid for testimony is baseless. He was only (appropriately) reimbursed for lost time. Another court rejected Ravgen's argument in a prior case. *Quest*, No. 21-cv-9011 (CDCA) (denying MIL 10).

Finally, Dr. Collins invented the "StabilCyte" art discussed above and has factual knowledge regarding its use. His testimony should be permitted for the same reasons the art itself should be permitted. Moreover, Ravgen has already deposed Collins, his prior deposition has been produced in this case, and Natera plans to rely on only his prior testimony; he will not be called live.

Supplementation is a two-way street. The case should be tried on a complete record—not just the evidence Ravgen seeks to add.

Requested Relief. Order that "Plaintiff's request to strike Wolfgang Holzgreve and Daniel Collins from Natera's June 23, 2023 Third Supplemental Initial Disclosures is hereby DENIED."

After consideration, including hearing oral argument on Ravgen's Motions on July 10, 2023, the Court finds that the Motions should be **DENIED**.

SO ORDERED, this 21st day of July, 2023.

ALAN D ALBRIGHT

UNITED STATES DISTRICT JUDGE